Eliem Therapeutics Provides Update on Pipeline Progress

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Company is positioned to initiate Phase 2a trial in major depressive disorder (MDD) in the first quarter of 2023

ETX-155 demonstrating exposures in single dose 60-milligram cohorts of ongoing Phase 1 pharmacokinetic trial that are consistent with prior clinical trials

Progressing into IND-enabling studies for two Kv7 pre-candidates

SEATTLE and CAMBRIDGE, United Kingdom, Oct. 05, 2022 (GLOBE NEWSWIRE) -- Eliem Therapeutics, Inc. (Nasdaq: ELYM), a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems, today provided an update on its pipeline programs, including the announcement of interim results from its ongoing Phase 1 clinical trial of ETX-155.

"I am tremendously grateful for the extraordinary effort put forth by our team to bring the ETX-155 program back on track while taking the time to understand the pharmacokinetic profile in order to have the right exposure levels to progress to Phase 2a. Based on the compound's favorable safety, tolerability, pharmacokinetic profile, and preclinical efficacy to date, we believe we are now well positioned to evaluate the efficacy and safety of ETX-155 in patients with MDD, which represents an important milestone for Eliem," said Bob Azelby, chief executive officer of Eliem Therapeutics. "We are also very excited about advancing two pre-candidates from our Kv7 program into IND-enabling studies. Both ETX-155 and Kv7 represent compelling product opportunities with the potential to be clinically differentiated drugs within classes where there is strong precedent clinical validation in depression and epilepsy, respectively. We remain well capitalized to bring these programs through key clinical data catalysts."

ETX-155 program: ETX-155 is a novel $GABA_A$ receptor positive allosteric modulator ($GABA_A$ PAM) that is being developed for the treatment of major depressive disorder (MDD) and epilepsy. Following the observation of lower-than-expected drug exposure levels in the three subjects evaluated in a Phase 1b photosensitive epilepsy (PSE) trial, the Company initiated a Phase 1, single and repeat dose, clinical trial in healthy subjects to confirm the pharmacokinetic profile of ETX-155 in advance of a planned Phase 2a clinical trial in subjects with MDD. The drug exposure levels from the recently executed single dose part of the Phase 1 pharmacokinetic trial (N=42) were compared with the population pharmacokinetic model built with data from healthy subjects evaluated in the original, previously disclosed Phase 1 trials (N=70). Results demonstrated that at the 60-milligram dose, there was no meaningful difference between exposures obtained with different batches, and that the low exposures observed in the Phase 1b PSE trial are within the range of previously reported moderate variability. In addition, and upon extensive investigation, no irregularities or differences were observed with chemistry, manufacturing, and controls (CMC) associated with the drug product and the drug substance batches used in the PSE trial or with other newly produced drug substance and product.

Given the encouraging safety, tolerability, and pharmacokinetic profile of the 60-milligram dose in the prior two Phase 1 repeat dose trials and well-tolerated single dose data with a 75-milligram dose in the ongoing Phase 1 pharmacokinetic trial, the Company plans to evaluate a 75-milligram dose of ETX-155 in the repeat dose part of the ongoing Phase 1 pharmacokinetic trial in healthy subjects prior to making a decision on the dose for the planned Phase 2a MDD trial. Final results from the Phase 1 pharmacokinetic trial, including the repeat dose cohort, are expected in the fourth quarter of 2022. The Company is positioned to initiate the Phase 2a MDD trial in the first quarter of 2023 using either the 60-milligram or 75-milligram dose of ETX-155, depending on the final exposure, safety and tolerability results from the ongoing Phase 1 pharmacokinetic trial. Assuming initiation in the first quarter of 2023, the topline data for the Phase 2a MDD trial would be expected in mid-2024.

The Company also has determined it will not reinitiate the PSE proof-of-concept trial but will continue to pursue development of ETX-155 in focal onset seizures (FOS), given compelling existing clinical validation of the $GABA_A$ PAM mechanism in this indication.

Kv7.2/3 channel opener program: The Company's preclinical program targets the Kv7.2/3 potassium channel (Kv7), a target that has clinical validation in pain and epilepsy. The Company has filed foundational intellectual property claims on its novel Kv7 compounds. In addition, while pursuing further lead evaluation, the Company has initiated the scaling up of two pre-candidates to enable the initiation of IND-enabling safety studies, expected in the first quarter of 2023, with Phase 1 studies planned to initiate in the first half of 2024. The Company's novel Kv7 compounds have demonstrated high potency and differentiated selectivity in electrophysiology assays, and in vivo anticonvulsant activity in the maximal electroshock seizure (MES) rat model. Preclinical data on the Kv7 compounds are planned to be reported later in the fourth quarter of 2022.

Anxiolytic for generalized anxiety disorder (GAD): The Company has discontinued early preclinical development of a novel, non-sedating anxiolytic for the potential treatment of GAD because none of the compounds investigated achieved the required profile.

Cash position: The Company's unaudited cash, cash equivalents, and investments as of September 30, 2022 were $129.8 million, including receipt of $6.2 million in tax reimbursements within the quarter, which is expected to fund operations into 2025.

About Eliem Therapeutics, Inc.

Eliem Therapeutics, Inc. is a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems. These disorders often occur when neurons are overly excited or inhibited, leading to an imbalance, and our focus is on restoring homeostasis. We are developing a pipeline of clinically differentiated product candidates focused on validated mechanisms of action with broad therapeutic potential to deliver improved therapeutics for patients with these disorders. Eliem channels its experience, energy, and passion for improving patients' quality of life to fuel our efforts to develop life-changing novel therapies. At its core, the Eliem team is motivated by the promise of helping patients live happier, more fulfilling lives.
https://eliemtx.com/

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements relating to: the advancement of Eliem's pipeline; the continued development and clinical and therapeutic potential of ETX-155 and Eliem's Kv7.2/3 channel opener program; Eliem's plan to study a 75-milligram repeat dose in the ongoing Phase 1 pharmacokinetic trial of ETX-155 and expected timing for the availability of final results from that trial; Eliem's belief that it is positioned to commence the referenced Phase 2a trial of MDD in the first quarter of 2023; Eliem's plans to continue to pursue development of ETX-155 in focal onset seizures; Eliem's planned activities and expectations for the Kv7.2/3 channel opener program, including the initiation of Phase 1 studies, and the timing thereof; Eliem's plans to report preclinical data on the Kv7 program later in the fourth quarter of 2022; Eliem's belief that ETX-155 and Kv7 represent compelling product opportunities with the potential to be clinically differentiated drugs; Eliem's belief that it is well capitalized and that its current cash, cash equivalents and short- and long-term marketable securities will fund operations into 2025; and Eliem's commitment to developing therapies targeting neuronal excitability disorders. Words such as "advancing," "assuming," "believe," "compelling," "continue," "excited," "expected," "focus," "initiate," "on track," "plans," "positioned," "potential," "progress," "pursue," "will," "would," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. The forward-looking statements in this press release are based upon Eliem's current plans, assumptions, beliefs, expectations, estimates and projections, and involve substantial risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements due to these risks and uncertainties as well as other factors, which include, without limitation: the clinical, therapeutic and commercial value of ETX-155 and the Kv7 program; risks related to the potential failure of ETX-155 or the Kv7 program to demonstrate safety and efficacy in clinical testing; Eliem's ability to initiate and conduct clinical trials and studies of ETX-155 or the Kv7 program sufficient to achieve a positive completion; the availability of data at the expected times; Eliem's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; the uncertain timing and level of expenses associated with Eliem's preclinical and clinical development activities; the sufficiency of Eliem's capital and other resources; risks and uncertainties related to regulatory application, review and approval processes and Eliem's compliance with applicable legal and regulatory requirements; market competition; changes in economic and business conditions; impacts on Eliem's business due to external events, including health pandemics or other contagious outbreaks, such as the current COVID-19 pandemic; and other factors discussed under the caption "Risk Factors" in Eliem's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022. This filing is available on the SEC's website at www.sec.gov. Additional information will also be set forth in Eliem's other reports and filings it will make with the SEC from time to time. The forward-looking statements made in this press release speak only as of the date of this press release. Eliem expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Eliem's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Investors
Chris Brinzey
ICR Westwicke
chris.brinzey@westwicke.com
339-970-2843

Media
Marites Coulter
Verge Scientific
Mcoulter@vergescientific.com
415.819.2214